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IP Issues in State Funding of Life Sciences Research

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Ethical Issues

Edward R. Murrow: “Who owns the patent on [the polio] vaccine?”

Jonas Salk: “Well, the people, I would say. There is no patent. Could you patent the sun?”

interview on See It Now, April 12, 1955

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Ethical Issues

Patenting life sciences research results provides a flash point for 3 long-lived debates:

1. Patenting life
2. Patenting (parts of) humans
3. Patenting basic science research

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Current Sources of Life Sciences Research Funding

- Public
  - – Federal funding for broad classes of extramural research
  - – State funding for focused initiatives (e.g., Life Sciences Discovery Fund; Prop. 71)
  - – Municipal funding for focused initiatives
- Private
  - – Angel, venture capital and corporate
  - – Foundations and other non-profits

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Current Recipients of Life Sciences Research Funding

- Universities
- Research organizations & hospitals
- Government & government affiliated labs
- Start-up and established companies

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A Science Policy Issue

- What role does/should the government play in scientific research?
  - intramural vs. extramural
  - funding (or not)
  - tax incentives (or not)
  - direct prohibition
  - enable patent and other IP protection

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Patentability of Life Sciences Research Results

- Patenting life: “Anything under the sun made by man”
- Patenting humans:
  - – PTO prohibition on patenting whole humans
  - – Patents on genes, cell lines and other human parts have been granted
- Patenting basic science research
  - •Constitutional limitations?

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Patenting Science vs. Patenting Technology

- U.S. Constitution, "IP clause":

"The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;"

- Following the grammatical structure and "respective" term:
  - science/authors/writings
  - useful arts/inventors/discoveries

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Evolution of Federal Patent Policy as Model for State Patent Policy

- Through WWII Federal agencies did not assert ownership of even intramural patentable inventions
- Truman order changes this
- But extramural invention policy left to funding agency until Kennedy issues uniform policy
- Rejects one-size-fits-all approach
- Two categories to determine who gets patent
  - directly usable inventions (Dept. of Agriculture)
  - inventions requiring mediating entity (NIH, NASA)

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Evolution of Federal Patent Policy as Model for State Patent Policy

- Bayh-Dole and commercialization of university labs
- Also brings one-size-fits-all policy: extramural lab/entity gets patent
- Kennedy policy introduced march-in rights; continued through Bayh-Dole
- Combination of Bayh-Dole effects and convergence of basic and applied research leads to patents moving increasingly “upstream”
- Upstream patents on basic science create controversy

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Key IP Issues for State Funding of Life Sciences Research

- Ownership of resultant patents
- Conflicts of ownership allocation & rights with other funding sources
- Retention of some rights by state
  - rights for state use
  - rights for commercial use
- Recoupment of funding vs. participation in profits in the case of successful patents
- *Compatibility with* vs. *copying of* Bayh-Dole
- Balancing commercialization incentives with access to essential medicines and therapies